4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2009-D-0503]

Guidances for Industry and Food and Drug Administration Staff: Computer-Assisted Detection Devices Applied to Radiology Images and Radiology Device Data--Premarket Notification (510(k)) Submissions; and Clinical Performance Assessment: Considerations for Computer-Assisted Detection Devices Applied to Radiology Images and Radiology Device Data--Premarket Approval and Premarket Notification (510(k)) Submissions; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of two related guidance documents. The first guidance, entitled "Computer-Assisted Detection Devices Applied to Radiology Images and Radiology Device Data--Premarket Notification (510(k)) Submissions" (CADe 510(k) guidance), provides recommendations regarding premarket notification (510(k)) submissions of certain computer-assisted detection (CADe)[1] devices applied to radiology images and radiology device data. The second guidance, entitled "Clinical Performance Assessment: Considerations for Computer-Assisted Detection Devices Applied to Radiology Images and Radiology Device Data--Premarket Approval (PMA) and Premarket

[1] The use of the acronym CADe for computer-assisted detection may not be a generally recognized acronym in the community at large. It is used here to identify the specific type of devices discussed in this document.

Notification (510(k)) Submissions" (CADe clinical performance assessment guidance), provides recommendations on the design and conduct of clinical performance studies for CADe devices applied to radiology images and radiology device data.

DATES: Submit either electronic or written comments on this guidance at any time. General comments on Agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the guidance document entitled "Computer-Assisted Detection Devices Applied to Radiology Images and Radiology Device Data--Premarket Notification (510(k)) Submissions" or the guidance document entitled "Clinical Performance Assessment: Considerations for Computer-Assisted Detection Devices Applied to Radiology Images and Radiology Device Data--Premarket Approval (PMA) and Premarket Notification (510(k)) Submissions" to the Division of Small Manufacturers, International, and Consumer Assistance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4613, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301-847-8149. See the SUPPLEMENTARY INFORMATION section for information on electronic access to these guidances.

Submit electronic comments on the guidances to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

I. Background

CADe devices are computerized systems that incorporate pattern recognition and data analysis capabilities (i.e., combine values, measurements, or features extracted from the patient radiological data) intended to identify, mark, highlight, or in any other manner direct attention to portions of an image, or aspects of radiology device data, that may reveal abnormalities during interpretation of patient radiology images or patient radiology device data by the intended user (i.e., a physician or other health care professional).

The CADe 510(k) guidance provides recommendations on documentation and performance testing to be part of a 510(k) submission for class II CADe devices applied to radiology images and radiology device data. The CADe clinical performance assessment guidance provides recommendations regarding clinical performance studies for both class II and class III CADe devices applied to radiology images and radiology device data. These clinical performance studies may be part of a premarket submission to FDA, whether it is a 510(k) submission, an application for PMA, an application for a humanitarian device exemption, or an application for an investigational device exemption.

In the Federal Register of October 21, 2009 (74 FR 54053), FDA announced the availability of the draft guidance documents. Interested persons were invited to comment by January 19, 2010. Six comments were received with multiple recommendations about changes to the content of the documents. FDA also received comments during the public meetings of the Radiology Devices Panel, an FDA advisory committee, on March 4-5, 2008, and November 17-18, 2009. In response to all of these comments, FDA revised both guidance documents to clarify the level of detail the Agency would like to see regarding the description and operation of the CADe device and about test data reuse. In response to the comments, the new guidance documents also clarify that digitized film is within the scope of radiological data and that FDA intends to create new product codes as necessary to identify and track new types of CADe products.

FDA's revisions, based on comments on the CADe 510(k) guidance, also include updated recommendations on the scoring process and when a clinical performance assessment may be necessary. The Generalizability Testing subsection was extensively modified, including removing recommendations on algorithm stability testing. In response to comments on the

CADe clinical performance assessment guidance, FDA limited the postmarket section to outlining the basic postapproval study process.

II. Significance of Guidance

These guidances are being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidances represent the Agency's current thinking on premarket notification (510(k)) submissions of certain CADe devices applied to radiology images and radiology device data and on clinical performance studies for CADe devices applied to radiology images and radiology device data. The guidance documents do not create or confer any rights for or on any person and do not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

III. Electronic Access

Persons interested in obtaining a copy of either guidance may do so by using the Internet. A search capability for all CDRH guidance documents is available at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm. Guidance documents are also available at http://www.regulations.gov. To receive "Computer-Assisted Detection Devices Applied to Radiology Images and Radiology Device Data--Premarket Notification (510(k)) Submissions," or "Clinical Performance Assessment: Considerations for Computer-Assisted Detection Devices Applied to Radiology Images and Radiology Device Data--Premarket Approval (PMA) and Premarket Notification (510(k)) Submissions," you may either send an email request to dsmica@fda.hhs.gov to receive an electronic copy of the document or send a fax request to 301-847-8149 to receive a hard copy. Please use the document number (1697) to identify the CADe 510(k) guidance or the document number (1698) to identify the CADe clinical performance assessment guidance.

IV. Paperwork Reduction Act of 1995

These guidance documents refer to currently approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in 21 CFR part 801 have been approved under OMB control number 0910-0485; the collections of information in 21 CFR part 807, subpart E, have been approved under OMB control number 0910-0120; the collections of information in 21 CFR part 812 have been approved under OMB control number 0910-0078; and the collections of information in 21 CFR part 814 have been approved under OMB control numbers 0910-0231 and 0910-0332.

V. Comments

Interested persons may submit to the Division of Dockets Management (see ADDRESSES), either electronic or written comments regarding this document. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: June 27, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

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